

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D2058078	(X3) Date Survey Completed 05/27/2021
Name of Provider or Supplier Pinnacle Dermatology	Street Address, City, State 595 William Latham Senior Dr, Bourbonnais, IL	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D5200	<p>GENERAL LABORATORY SYSTEMS CFR(s): 493.1230</p> <p>Each laboratory that performs nonwaived testing must meet the applicable general laboratory systems requirements in 493.1231 through 493.1236, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the general laboratory systems and correct identified problems specified in 493.1239 for each specialty and subspecialty of testing performed.</p> <p>This CONDITION is not met as evidenced by: Based on record review, lack of documentation, previous Plan of Correction (POC) received 02/14/2019, and interview with the testing personnel (TP2); the laboratory failed to properly manage and evaluate the overall quality of testing. The laboratory must meet the requirements in 493.1231 through 493.1236 in the specialty of Histopathology. Findings include: 1. The laboratory failed to verify the accuracy bi-annually for Mohs surgery tissue processing procedures performed. See D5217.</p>
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: REPEAT DEFICIENCY Based on records review, lack of documentation, the Plan of Correction (POC) received on 02/14/2019, and an interview with testing personnel (TP2), the laboratory failed to verify the accuracy of the Histopathology testing the laboratory performed for the years of 2019, 2020 and 2021. Findings include: 1. The</p>

laboratory quality assurance log book, Mohs patients' logs, POC received on 02/14/2019, and manual were reviewed. 2. The patients' test logs revealed the laboratory had been performing Mohs surgery procedures during the years of 2019, 2020, and 2021. 3. The documentation showed the laboratory had not verified the accuracy of its Mohs procedure during the years listed in Findings #2. 4. Further review revealed the laboratory has not performed biannual verification procedures since 12/01/2018. 5. The laboratory continued to fail to follow quality assurance procedures and the POC received on 02/14/2019 to verify the accuracy it's Mohs surgery procedure at least twice annually, for the years of 2019 through 2021. 6. On a Recertification survey conducted on 05/27/2021 at 3:50 PM, the TP2 confirmed the above findings.